

### **REMARKS**

Reconsideration of the captioned application as amended herewith is respectfully requested.

This preliminary amendment is filed concurrently with a petition for a **one month extension of time** to extend the date of response to the Office Action from 26 May 2005 to 26 June 2004.

The Office Action:

- a) rejected claims 2 – 24, 26 – 22, and 24 – 26 under 35 USC §112, second paragraph, as being indefinite;
- b) rejected claims 2 – 24, 16 – 22, 24-26, and 72 under 35 USC §103(a) by JP 2-53271 to Okada et al. ("Okada") in view of United States Patent No. 6,139,865 to Friend, et al. ("Friend") and CA 2068366 ("Abstract").

Claims 1, 12, 15, 23, and 37 - 72 were cancelled. Claims 2 – 11, 13 -14, 16 – 22, 24 – 36, and 73 remain pending in this application after entry of this amendment.

Claims 8, 18, 22, 26, 30, and 31 were amended to highlight patentable features of the present invention. Support for these amendments may be found in the Specification as originally filed at, for example, page 5, lines 27 - 29, and as such does not introduce new matter into the application under 37 CFR 1.121.

#### **The Rejection of Claims 2 – 14, 16 22, and 24 – 36 Under 35 USC §112, Second Paragraph, Should Be Withdrawn**

Claims 2 – 24, 16 – 22, and 24 - 36 stand rejected under 35 USC §112, second paragraph, as indefinite for allegedly failing to particularly point out and distinctly claim the subject matter of the invention. In view of the amendments to claims 8, 18, 26, and 31 in which the language regarding "USP dissolution specifications" was removed, Applicants respectfully submit that the rejection of independent claims 8, 18, 26, and 31 under 35 USC §112, second paragraph, has been overcome and should be withdrawn.

Claims 2, 3, 4, 5, 6, 7, 9, 10, 11, 13, and 14, which are dependent upon claim 8 and incorporate all of its limitations therein, are likewise also patentable under 35 USC §112, second paragraph in view of the above.

Claims 16, 17, 19, 20, 21, and 22, which are dependent upon claim 18 and incorporate all of its limitations therein, are likewise also patentable under 35 USC §112, second paragraph in view of the above.

Claims 24, 25, 27, 28, 29, and 30, which are dependent upon claim 26 and incorporate all of its limitations therein, are likewise also patentable under 35 USC §112, second paragraph in view of the above.

Claims 32 - 36, which are dependent upon claim 31 and incorporate all of its limitations therein, are likewise also patentable under 35 USC §112, second paragraph in view of the above.

**The Rejection of Claims 2 – 24, 16 – 22, 24 – 36, and 72 under 35 USC §103(a) as Unpatentable Over Okada in view of Friend and Abstract Should Be Withdrawn**

Claims 2 – 24, 16 – 22, 24 – 26, and 72 stand rejected under 35 USC §103(a) as unpatentable over Okada in view of Friend and Abstract. Applicants respectfully disagree for the reasons that follow.

Okada discloses the use of granules coated by a “protective film,” which “protect... the granules so that the functions of the film of the coated granules essentially do not change when it is administered to an individual and so that they are resistant to compressive force when compression is applied.” Okada, page 2. One such suitable protective film includes 6.5% hydroxypropyl methyl cellulose and 0.5% of a polyethylene glycol. See Okada, Example 3. Therefore, at best, Okada discloses the use of a film containing hydroxypropyl methyl cellulose and polyethylene glycol in a 13:1 ratio.

By contrast, the invention as presently claimed incorporates a “second coating layer on the surface of the first coating layer, the second coating layer comprised of

- i) a film forming polymer; and
- ii) an anti-grit agent,

wherein the weight ratio of film forming polymer to anti-grit agent in the second coating layer is in the range of about 10:90 to about 90:10" (emphasis added). As disclosed in the Specification at page 5, lines 27 – 29, this coating layer is incorporated into Applicants' claimed invention in these amounts in order to provide texture masking properties to the core.

Okada neither discloses nor suggests the use of a coating layer for texture masking purposes, but rather teaches the use of films for protecting the granules. Okada further neither discloses nor suggests the use of a coating layer containing a film forming polymer and an anti-grit agent within the claimed ratio. Instead, Okada only illustrates one type of its "protective layer" film in only one example, and the film of that one example uses ingredients that are well above the range claimed by Applicants. Furthermore, Okada fails to disclose or suggest the need or the method for modifying its "protective film," let alone the need or the method for modifying such a "protective film" in order to provide texture masking properties.

Friend and the Abstract also fail to disclose or suggest the need or the method for modifying the "protective film" of Okada, let alone the need or the method for so modifying the "protective film" in order to modify it into a coating like the "second coating layer comprised of i) a film forming polymer; and ii) an anti-grit agent, wherein the weight ratio of film forming polymer to anti-grit agent in the second coating layer is in the range of about 10:90 to about 90:10" (emphasis added) as claimed herein. Rather, Friend and Abstract only exemplify certain components suitable for tastemasking agents, such as those suitable for Applicants "first coating layer comprised of a taste masking agent." (emphasis added)

Therefore, Applicants respectfully submit that if one were to combine Okada with Friend and/or the Abstract as proposed in the Office Action, the resulting dosage form would not possess the second coating layer as presently claimed. Because the combination of these references fail to disclose or suggest the claimed invention, "second coating layer comprised of i) a film forming polymer; and ii) an anti-grit agent, wherein the weight ratio of film forming polymer to anti-grit agent in the second coating layer is in the range of about 10:90 to about 90:10 ." (emphasis added) Applicants respectfully submit that the rejection of independent claims 8, 18, 26, 31, and 73 under 35 USC §103(a) as unpatentable over Okada in view of Friend and Abstract has been overcome and should be withdrawn.

Claims 2, 3, 4, 5, 6, 7, 9, 10, 11, 13, and 14, which are dependent upon claim 8 and incorporate all of its limitations therein, are likewise also patentable over the combination of Okada in view of Friend and Abstract in view of the above.

Claims 16, 17, 19, 20, 21, and 22, which are dependent upon claim 18 and incorporate all of its limitations therein, are likewise also patentable over the combination of Okada in view of Friend and Abstract in view of the above.

Claims 24, 25, 27, 28, 29, and 30, which are dependent upon claim 26 and incorporate all of its limitations therein, are likewise also patentable over the combination of Okada in view of Friend and Abstract in view of the above.

Claims 32 - 36, which are dependent upon claim 31 and incorporate all of its limitations therein, are likewise also patentable over the combination of Guley in view of Okada in view of Friend and Abstract in view of the above.

The Office Action also stated that claim 72 was also rejected under 35 USC §103(a) as unpatentable over Okada in view of Friend and Abstract. Applicants respectfully submit that this rejection has been overcome and should be withdrawn in view of the fact that claim 72 is cancelled. Although not expressly rejected in the Office Action, Applicants further respectfully submit that claim 73 is patentable for reasons such as, for example, those set forth above with respect to claim 8.

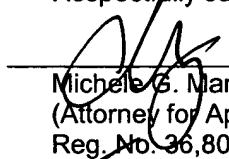
**Conclusion**

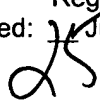
It is submitted that the foregoing amendments and remarks place the case in condition for allowance. A notice to that effect is earnestly solicited.

In the event that all of the claims are not in condition for allowance, Applicants respectfully request for an interview with the Examiner before the preparation of the next Office Action.

Respectfully submitted,

By: \_\_\_\_\_

  
Michele S. Mangini  
(Attorney for Applicants)  
Reg. No. 36,806

Dated:  June 2004

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(732) 524-2810  
MCP231.Amt.6.04.doc